SUBJECT: MANAGEMENT OF CONTROLLED SUBSTANCES FOR ALS AGENCIES **Date: 9/1/2010**

I. Authority: California State Board of Pharmacy Business and Professions Code, Section 4119and 4126.5, California Code of Regulations, Title 22, Division 2.5, Chapter 3, Section 1797.172, and Chapter 5, Section 1798 through 1798.6, and Title 21, Chapter II of the Code of Federal Regulations, Sections 1301.11; 1301.12; 1301.75; 1301.76; 1301.91; 1301.92; 1304.03; 1304.04; 1304.11; 1304.211304.22; 1307.02; 1307.21; 1305.05

II. Purpose: To ensure accountability for all controlled substances and devices issued to advanced life support (ALS) units.

III. Policy: All Advanced Life Support (ALS) Agencies in the County of San Diego will have a physician registrant to purchase controlled substances with a Drug Enforcement Administration (DEA) Form 222 from a pharmacy, or pharmaceutical supply agency, thereby retaining ownership, accountability and responsibility of those controlled substances. ALS Agencies which do not have a Medical Director may use the County of San Diego EMS Medical Director to assist with the purchase of controlled substances (per Policy S-416) if said agency signs a Memorandum of Agreement with the County of San Diego, for the purchase of Dangerous Drugs and Devices. All ALS agencies will develop policies compliant with Title 21 CFR regulations concerning the procurement, receipt, distribution and waste management of controlled substances managed under their DEA registration number.

IV. Definitions:

Controlled Substances: Pharmaceutical drugs categorized as Schedule II, III or IV by the DEA.

ALS Units – Ambulances or other emergency vehicles (e.g. engines, trucks etc.) upon

which paramedics are placed to render ALS care.

V. Procedure:

A. Initial Stocking and resupply of ALS Units:

1. Controlled substances will be ordered by the agency physician registrant and assigned to its ALS Units according to Drug Enforcement regulations.
2. All controlled substances will be issued in tamper evident containers and must be kept under double lock and key system.
3. All ALS agencies will maintain a stock supply of controlled substances at a central location at which all that agency's ALS units must resupply.
4. If any ALS agency wishes to have more than one location from which to stock ALS units, each location will have a separate DEA registration.
5. All locations in an ALS agency shall be under the control of the agency person who is designated to manage the narcotics program at the agency for the Medical Director.
6. All ALS agencies will maintain a secure, double locked location in which to keep the stock supply of the controlled substances. Access to this supply will be strictly limited.
7. All ALS agencies will be subject to at least yearly inspection of the location of the controlled substances and the logs in the storage location, by the physician registrant or designee.

B. Controlled Substance Record keeping by ALS Agency registrants:

1. All ALS agencies will keep a controlled substance log in the secure location that will

document:

a. Receiving of the controlled substances.

b. Distribution of controlled substances to the units for restock

c. Daily count of controlled substances

2. All registered agencies shall maintain the following logs on site for DEA review at any time (n. b. inventory records must be kept separately from the logs):

   a. Initial inventory (documented at the initial registration of the agency)

      (1) A physical count of all controlled substances in stock, to include on the vehicles is to be taken.

      (2) Enter this count on an inventory record.

   b. A biennial inventory is then taken each two years beginning within two years of the initial stocking date.

3. All original controlled substance purchase invoices and executed DEA-222 forms must be kept separately from the daily and maintenance logs.

4. The following logs must be maintained at the agency for a period of not less than 2 years.

   a. Controlled Drug Usage Record

   b. Controlled Drug Inventory Record

   c. Records for Schedule II narcotics (Morphine Sulfate, and Morphine Immediate Release Oral Liquid) must be maintained separately from Schedule IV drugs (Midazolam).

C. Record–keeping on ALS Units:

1. Each ALS Unit shall maintain a standardized written record of controlled drug inventory. That record shall be available to the physician registrant for routine inspection, and shall be maintained by the agency for a period of three (3) years in compliance with the State Board of Pharmacy.
2. Drugs shall be inventoried by the ALS Personnel at the beginning and at the conclusion of each shift, and documentation shall include the signatures of the person(s) performing the inventory and noted on the controlled drug inventory.
3. Any time a controlled substance is administered, the name of the drug, the dose administered, the date of administration, the patient name, the name of the licensed person who is administering the medication, the receiving facility and the QCS run number, if available, shall be documented on the controlled drug inventory.
4. Any medication that has not been completely used must be disposed of in the presence of two medical personnel.
5. Agency personnel must document any disposed narcotic on the appropriate agency form. This form must document:
    a. The amount of the medication given to the patient
    b. The amount of the medication disposed
    c. The signatures of the two medical personnel who witnessed the disposal.

D. Management of Inventory Discrepancies

1. Any discrepancy between the written ALS Unit controlled drug inventory and the count of on board or stock supply drugs shall be noted on the controlled drug inventory sheet and shall be signed by the ALS Team first noting the discrepancy.

That discrepancy shall be verbally reported immediately to the agency person responsible for the narcotics at the agency.

2. Any discrepancy between the inventory and the actual amounts of the narcotics in the stock supply must be reported immediately to the physician registrant, followed by written report to the EMS Branch within 24 hours.
3. Any discrepancy between the inventory and the actual amounts of the narcotics in the stock supply must be reported to the DEA immediately using form P-106 on the DEA Diversion website (www.deadiversion.usdoj.gov).
4. Any agency personnel having knowledge of drug diversion must report this situation to the DEA.

E. Controlled Drug Inspection/Audit of ALS Units:

1. Periodic unannounced inspections or audits of controlled drugs and/or controlled drug inventory shall be conducted no less than once each year by the physician registrant or designee.
2. The EMS Medical Director or designee may perform announced or unannounced periodic inspections to document compliance with this policy at any time.